IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

KATHERINE CROCKETT, Plaintiff, v. LUITPOLD PHARMACEUTICALS, INC; AMERICAN REGENT, INC.; DAIICHI SANKYO, INC.; DAIICHI SANKYO CO., LTD.; DAIICHI SANKYO US HOLDINGS, INC.; VIFOR (INTERNATIONAL) AG, Defendants.	NO: 2:19-CV-00276 **JURY TRIAL DEMANDED**

DEFENDANT VIFOR (INTERNATIONAL) AG'S AMENDED ANSWER TO PLAINTIFF'S THIRD AMENDED COMPLAINT

Defendant, Vifor (International) AG ("Vifor International" or "Defendant"), by and through its counsel of record hereby sets forth the following Amended Answer to Plaintiff's Third Amended Complaint ("Answer"). Defendant responds to the allegations in Plaintiff's Third Amended Complaint ("Complaint") insofar as the allegations pertain to it. Except as otherwise expressly set forth below, Defendant denies knowledge or information sufficient to form a belief as to the truth or falsity of each and every allegation in the Complaint to the extent that such allegations refer or relate to any other defendant, person or entity. Any allegations, averments, contentions or statements in the Complaint not specifically and unequivocally admitted in this Answer are denied. Defendant responds to each of the paragraphs of the Complaint as follows:

PARTIES, JURISDICTION, AND VENUE[1]

1. Plaintiff, Katherine Crockett, is a resident of Philadelphia, PA.

[1] Defendant repeats the Complaint's subheadings solely for organizational purposes and does not admit to their truth.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

American Regent Defendants[2]

2. Luitpold Pharmaceuticals, Inc. (hereinafter "Luitpold") was a for-profit corporation incorporated in the state of New York. At all relevant times, Luitpold maintained its principal offices in Norristown, PA and Shirley, NY. Luitpold was a subsidiary and member of the Daiichi Sankyo Group and was the parent company to its own subsidiary, American Regent, Inc. In addition to maintaining an office in the Commonwealth of Pennsylvania, Luitpold was registered to do business throughout the state as well as in the county of Philadelphia, specifically. Luitpold has at all relevant times engaged in the business of researching, developing, testing, designing, licensing, manufacturing, distributing, selling, labeling, promoting, and marketing the Injectafer (*ferric* carboxymaltose) product.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

3. American Regent, Inc. (hereinafter "American Regent") is a for-profit corporation incorporated in the state of New York. At all relevant times, American Regent appears to operate its principal office out of Shirley, NY, sharing an office address with Luitpold. Upon information and belief, American Regent also operates out of its Norristown, PA office and is registered to do business in the Commonwealth. American Regent was originally a subsidiary of Luitpold and the Daiichi Sankyo Group. American Regent is the manufacturer listed on the Injectafer label. Along

[2] Upon information and belief, the American Regent, Inc. entity named as a defendant in Plaintiff's Complaint was a wholly-owned subsidiary of Luitpold Pharmaceuticals, Inc. and no longer exists. To streamline its business, Luitpold Pharmaceuticals, Inc. merged this entity into itself on December 31, 2018. Thereafter, the surviving entity was renamed American Regent, Inc. Herein, Defendant's use of "American Regent, Inc." or "ARI" refers to all of the new surviving entity, the former Luitpold Pharmaceuticals, Inc., and the former American Regent, Inc.

with Defendant Luitpold, American Regent is and was at all relevant times engaged in the business of researching, developing, testing, designing, licensing, manufacturing, promoting, labeling, distributing, selling, and marketing the Injectafer product.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them. In addition, as to footnote 1 of the Complaint, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations and, therefore, denies them.

4. Upon information and belief, on or about December 31, 2018, Luitpold merged American Regent into itself, and the surviving entity – Luitpold – was renamed American Regent, Inc. The new entity of American Regent is wholly owned by Daiichi Sankyo, Inc.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

Daiichi Sankyo Defendants

5. Daiichi Sankyo, Inc. (hereinafter "DSI") is a for-profit corporation incorporated in the state of Delaware with its principal office in Basking Ridge, New Jersey. Upon information and belief, DSI is or was also known as Sankyo USA Development, Sankyo Pharma Development, Sankyo Pharma Inc., Daiichi Sankyo Pharma Development, Daiichi Pharmaceuticals, Inc., Daiichi Medical Research, Inc., Daiichi Sankyo Group, and Daiichi Pharma Holdings, Inc. The below allegations are attributable to all such entities now represented by DSI or Daiichi Sankyo Co., Ltd.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

6. DSI is the United States subsidiary of Daiichi Sankyo Co., Ltd, located in Tokyo, Japan, and is a member of the Daiichi Sankyo Group. Upon information and belief, both Defendants Luitpold and American Regent are and were members of the Daiichi Sankyo Group.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

7. DSI is wholly owned by Defendant, Daiichi Sankyo U.S. Holdings, Inc.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

8. DSI is and was at all times engaged in the business of researching, developing, designing, licensing, manufacturing, and distributing, and selling the Injectafer product. Additionally, DSI specifically assumed the roles of promoting and marketing Injectafer in or around January 2017.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

9. Daiichi Sankyo Co., Ltd. (hereinafter "DSC") is the parent company to DSI, Daiichi Sankyo U.S. Holdings, Inc., and the Daiichi Sankyo Group of companies. At all relevant times, DSC is and was a corporation organized and existing under the laws of Japan, having its principal place of business at 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo, 103-8426, Japan.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

10. DSC is in the business of designing and manufacturing prescription drugs, including that used by Plaintiff, across the world, including in the United States, and specifically in the Commonwealth of Pennsylvania.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

11. Upon information and belief, DSC at all relevant times exercised control over DSI and the DSI subsidiaries, Luitpold and American Regent, as well as Daiichi Sankyo U.S. Holdings, Inc.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

12. Upon information and belief, the agreements between and among the Daiichi defendants, and their affiliates and subsidiaries, provides for DSC to have ultimate control over all relevant decisions, policies, and conduct, and therefore is liable for any and all tort liabilities of Defendants DSI, Luitpold, Daiichi Sankyo U.S. Holdings, Inc., and American Regent.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

13. Upon information and belief, DSI operates as the U.S. headquarters of DSC. At least four of the principals, members, directors, or officers of DSI are also members of DSC. In addition, DSC operates several research and development facilities across the world, including collaborating with DSC to oversee operations for its U.S. subsidiaries.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

14. Daiichi Sankyo U.S. Holdings, Inc. (hereinafter "DS Holdings") wholly owns Daiichi Sankyo, Inc. and is located in Basking Ridge, New Jersey.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

15. Upon information and belief, DS Holdings is a subsidiary of DSC.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

16. Upon information and belief, DS Holdings is and was at all times engaged in the business of researching, developing, designing, licensing, manufacturing, and distributing, and selling the Injectafer product.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

17. Upon information and belief, DS Holdings was responsible for the actions and omission of its wholly owned subsidiary, DSI.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

18. Upon information and belief, there existed at all relevant times a unity of interest in ownership between DSC, DS Holdings, and DSI such that independence from, or separation between, the Daiichi Defendants does not exist and has never existed. Each of them are alter egos of the other.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

19. Because of the unity of operations and ownership, DSI, DS Holdings, and DSC are hereto after referred to as the "Daiichi Defendants."

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

Vifor Defendants

20. Vifor Pharma Ltd. (hereinafter "Vifor Pharma") is a for-profit corporation headquartered in Switzerland with an office location at Rechenstrasse 37 CH-9014 St. Gallen.

ANSWER: Only Defendant Vifor International is answering this Complaint. Defendant admits only that Vifor Pharma is a for-profit corporation headquartered in St. Gallen, Switzerland. Defendant otherwise denies the allegations in this paragraph.

21. Vifor Pharma Participations Ltd. (hereinafter "Vifor Participations") is a for-profit corporation headquartered in Switzerland with an office location at Rechenstrasse 37 CH-9014 St. Gallen.

ANSWER: Only Defendant Vifor International is answering this Complaint. Defendant admits only that Vifor Participations is a for-profit corporation headquartered in St. Gallen, Switzerland. Defendant otherwise denies the allegations in this paragraph.

22. Vifor Participations is a wholly owned subsidiary of Vifor Pharma.

ANSWER: Only Defendant Vifor International is answering this Complaint. Defendant admits that Vifor Participations is wholly owned by Vifor Pharma. Defendant otherwise denies the allegations in this paragraph.

23. Vifor (International) AG a/k/a Vifor (International) Inc. (hereinafter "Vifor International") is a for-profit corporation headquartered in Switzerland with an office location at Rechenstrasse 37 CH-9014 St. Gallen.

ANSWER: Only Defendant Vifor International is answering this Complaint. Defendant admits that Vifor International is a for-profit corporation headquartered in St. Gallen, Switzerland. Defendant otherwise denies the allegations in this paragraph.

24. Vifor Pharma Management Ltd. (hereinafter "Vifor Management") is a for-profit corporation headquartered in Switzerland with an office location at Flughofstrasse 61, CH-81542 Glattbrugg.

ANSWER: Only Defendant Vifor International is answering this Complaint. Defendant admits only that Vifor Management is a for-profit corporation headquartered in Zurich-Glattbrugg, Switzerland. Defendant otherwise denies the allegations in this paragraph.

25. Vifor International and Vifor Management are both wholly owned subsidiaries of Vifor Participations, which is wholly owned by Vifor Pharma.

ANSWER: Only Defendant Vifor International is answering this Complaint. Defendant admits that Vifor Management and Vifor International are wholly owned by Vifor Participations, which is wholly owned by Vifor Pharma. Defendant otherwise denies the allegations in this paragraph.

26. Relypsa Inc. is a for-profit corporation incorporated in the state of Delaware with its principal office located at 100 Cardinal Way, Redwood City, California.

ANSWER: Only Defendant Vifor International is answering this Complaint. Defendant admits only that Relypsa, Inc. changed its name to Vifor Pharma, Inc. effective January 28, 2021, and is a for-profit corporation incorporated in Delaware and headquartered in Redwood City, California. Defendant otherwise denies the allegations in this paragraph.

27. Relypsa Inc. is a United States wholly owned subsidiary of Vifor Pharma, and a United States Corporate Affiliate of Vifor Management and Vifor International.

ANSWER: Only Defendant Vifor International is answering this Complaint. Defendant admits only that Relypsa, Inc. changed its name to Vifor Pharma, Inc. effective January 28, 2021, that it is wholly owned by Vifor Pharma and is a U.S. corporate affiliate of Vifor Management and Vifor International. Defendant otherwise denies the allegations in this paragraph.

28. Vifor Pharma is the parent company to Vifor Participations, Vifor International, Vifor Management, and Relypsa. At all relevant times, Vifor Pharma is and was a corporation organized and existing under the laws of Switzerland, having its principal place of business at Rechenstrasse 37 CH-9014 St. Gallen.

ANSWER: Only Defendant Vifor International is answering this Complaint. Defendant admits only that (1) Vifor International and Vifor Management are wholly owned by Vifor Participations, which is wholly owned by Vifor Pharma; (2) Relypsa, Inc. changed its name to Vifor Pharma, Inc. effective January 28, 2021, and is wholly owned by Vifor Pharma; and (3) Vifor Pharma is a corporation headquartered in St. Gallen, Switzerland. Defendant otherwise denies the allegations in this paragraph.

29. Because of the unity of operations and ownership, Vifor Pharma, Vifor Participations, Vifor International, Vifor Management, and Relypsa are hereto after referred to as the "Vifor Defendants."

ANSWER: Defendant admits only that Plaintiff, for purposes of the Complaint, defines "Vifor Defendants" as a term intended to include Vifor International. Only Defendant Vifor International is answering this Complaint. Defendant otherwise denies the allegations in this paragraph.

30. The Vifor Defendants are in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into commerce ferric carboxymaltose, or its European brand bioequivalent, Ferinject.

ANSWER: Defendant admits only that: (1) it researched, developed and designed ferric carboxymaltose; (2) it licenses the Active Pharmaceutical Ingredient ("API") to ARI for manufacture and use in the United States by ARI as "Injectafer;" and (3) it designs, manufactures and sells Ferinject in Europe. Defendant otherwise denies the allegations in this paragraph.

31. Upon information and belief, the Vifor Defendants, by and through Vifor International, are engaged in a licensing deal with Luitpold that permits Luitpold to design, manufacture, market, supply, promote, label, distribute, and sell Injectafer in the United States. Vifor International was the international "partner" of Luitpold in the sale of Injectafer. The licensing agreement between Vifor International and Luitpold awards Vifor International a "share of partner sales" in regards to Injectafer sales in the United States.

ANSWER: Defendant admits only that it licenses the API to ARI for manufacture and use in the United States by ARI as "Injectafer." ARI is and has

only ever been the sole New Drug Application ("NDA") holder for Injectafer in the United States, and is responsible for compliance with the Food and Drug Administration's ("FDA") regulatory requirements. Further, the responsibilities of Defendant Vifor International with respect to the licensing of the API to ARI are formally set forth in the Master Licensing Agreement, which speaks for itself. Defendant otherwise denies the allegations in this paragraph.

32. Upon information and belief, the Vifor Defendants were responsible for the original design and development of the bioequivalent ferric carboxymaltose product, Ferinject.

ANSWER: Defendant admits only that it designed and developed Ferinject which is not sold in the United States. Defendant otherwise denies the allegations in this paragraph.

33. Upon information and belief, the Vifor Defendants, by and through Vifor International, licensed that ferric carboxymaltose design to Luitpold, which in turn designed, manufactured, marketed, supplied, distributed, and sold the bioequivalent Injectafer product to the United States market.

ANSWER: Defendant admits only that it licenses the API to ARI for manufacture and use in the United States by ARI as "Injectafer." Defendant denies the remaining allegations in this paragraph.

34. Pursuant to the aforementioned licensing deal and other agreements, the Vifor Defendants assumed a role in the conducting and management of the clinical trials, marketing, promotion, marketing sales organization, and safety reporting for Injectafer.

ANSWER: Defendant admits only that the responsibilities of Defendant Vifor International with respect to the licensing of the API to ARI for manufacture and

use in the United States by ARI as "Injectafer," are formally set forth in the Master Licensing Agreement, which speaks for itself, and otherwise denies the remaining allegations in this paragraph.

35. Upon information and belief, the Vifor Defendants, by and through Relypsa, manage the United States iron business, including Injectafer, on behalf of Vifor International, and provide support to American Regent and DSI, on the design, manufacture, distribution, marketing, promotion, pharmacovigilance, and/or sale of Injectafer.

ANSWER: Denied.

36. Pursuant to 21 C.F.R. § 207 (2019), foreign manufacturers of a pharmaceutical drug that is imposed or offered into the United States must have a Registered Agent. Vifor's Registered Agent in the United States is American Regent.

ANSWER: This allegation constitutes a legal conclusion to which no response is required, and the Code of Federal Regulations speaks for itself. Defendant otherwise denies the allegations in this paragraph.

37. Additionally, since initially introducing ferric carboxymaltose into the world market, Vifor Pharma, and its subsidiaries have been in the business of collecting, supervising, analyzing, and reporting adverse events, peer-reviewed literature, clinical and nonclinical studies, and other epidemiology on ferric carboxymaltose.

ANSWER: Defendant admits only that the responsibilities of Defendant Vifor International with respect to the licensing of the API to ARI for manufacture and use in the United States by ARI as "Injectafer" are formally set forth in the Master Licensing Agreement and the Pharmacovigilance Agreement, which speak for themselves. ARI is and has only ever been the sole NDA holder for Injectafer in

the United States, and is responsible for compliance with the FDA's regulatory requirements. Defendant otherwise denies the allegations in this paragraph.

38. Each of the above Defendants played a role in the design, manufacture, distribution, marketing, promotion, pharmacovigilance, and/or sale of Injectafer. Plaintiff's injuries were caused by the conduct of one or various combinations of Defendants, and through no fault of Plaintiff.

ANSWER: Denied.

JURISDICTION AND VENUE

39. This Court has personal jurisdiction over Plaintiff, Katherine Crockett, who was a resident of Philadelphia, Pennsylvania, at all times relevant to the administration and treatment for Injectafer. Additionally, Plaintiff was administered the Injectafer product in Philadelphia, Pennsylvania, suffered her injuries caused by the drug in Philadelphia, Pennsylvania, and received and continues to receive substantial medical treatment for her injuries in Philadelphia, Pennsylvania. This Court has original jurisdiction over this matter pursuant to 28 U.S.C.S. § 1332 because the matter in controversy exceeds the sum of $75,000.00 and because it is between citizens of different states. *See* 28 U.S.C.S. § 1332(a)(1).

ANSWER: Defendant does not contest subject matter jurisdiction as to Vifor International, and otherwise denies allegations as to it in this paragraph. As to entities other than Defendant Vifor International, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

General Personal Jurisdiction

40. This Court has personal jurisdiction, pursuant to 42 Pa. C.S. § 5301 *et seq.*, over the Defendants because, at all relevant times, they have engaged in continuous and systematic business activities in the Commonwealth of Pennsylvania.

ANSWER: Defendant does not contest personal jurisdiction as to Vifor International, and Defendant otherwise denies the allegations as to it in this paragraph. As to entities other than Defendant Vifor International, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

41. This Court also has general personal jurisdiction over the Luitpold, American Regent, and DSI Defendants because each is registered to do business in Pennsylvania and therefore has consented to general personal jurisdiction in Pennsylvania, per 42 Pa. C.S. § 5301 and 42 Pa. C.S § 5322. DSC and DS Holdings, as the parents and alter ego to DSI and the Daiichi Sankyo Group, thus have inextricable ties to Pennsylvania.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

42. This Court also has general personal jurisdiction over the Vifor Defendants, which do business in Pennsylvania. Specifically, the Vifor Defendants, by and through Vifor International, engaged in a licensing deal for its ferric carboxymaltose product that would see the continuous and systematic sale of Injectafer in the Commonwealth. Additionally, the Vifor Defendants, by and through the Vifor affiliates including, but not limited to, Relypsa, manage the sale of Injectafer in the United States, including in the Commonwealth, and provide support to American Regent and DSI on the design, manufacture, distribution, marketing, promotion, pharmacovigilance, and/or sale of Injectafer. Vifor's Registered Agent is American Regent. Vifor

Pharma and Vifor Participations, as the parents and alter ego to Vifor International and Relypsa, thus have inextricable ties to Pennsylvania.

ANSWER: Defendant does not contest personal jurisdiction as to Vifor International. Defendant admits only that it licenses the API to ARI for manufacture and use in the United States by ARI as "Injectafer." Defendant otherwise denies the allegations in this paragraph.

43. This Court has additional grounds for general personal jurisdiction as Luitpold and American Regent operate an office and principal place of business at 800 Adams Street, Norristown (*also referred to as Eagleville or Audubon*), PA 19403, which is located in the Eastern District of Pennsylvania. *See* 28 U.S.C.S. § 1391(b)(1)&(2).

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

44. This Court also has personal jurisdiction over each of the Defendants pursuant to 42 Pa. C.S § 5322.

ANSWER: Defendant does not contest personal jurisdiction as to Vifor International, and Defendant otherwise denies the allegations as to it in this paragraph. As to entities other than Defendant Vifor International, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

Specific Personal Jurisdiction

45. This Court has specific personal jurisdiction over the Defendants due to the Injectafer-specific business activities, including but not limited to the development, testing,

pharmacovigilance, safety monitoring, promotion, and sale of Injectafer that take place in parts of the Commonwealth of Pennsylvania which are located in the Eastern District of Pennsylvania.

ANSWER: Defendant does not contest personal jurisdiction as to Vifor International, and Defendant otherwise denies the allegations as to it in this paragraph. As to entities other than Defendant Vifor International, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

46. Upon information and belief, Luitpold headquartered its Clinical Division at its Norristown, Pennsylvania office. Norristown, PA was also home to Luitpold's Clinical Research and Development Department, to the extent that group existed separately from the Clinical Division.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them. In addition, as to footnote 2 of the Complaint, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this footnote and, therefore, denies them.

47. Upon information and belief, Luitpold's senior Clinical and scientific staff conducted their Injectafer-specific responsibilities out of the Norristown, PA office, including the Senior Clinical Project Manager responsible for Injectafer.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

48. Upon information and belief, Luitpold's Regulatory Affairs Department also operated out of the Norristown, PA office. Specifically, Marsha E. Simon, Director of Regulatory

Affairs, was employed in the Norristown, PA office and used the Norristown, PA address when making regulatory submissions on behalf of Luitpold and Injectafer to the Food and Drug Administration (FDA).

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

49. Additionally, the Luitpold Norristown PA office served as either the monitoring hub, organizational headquarters, or specific location for pivotal Injectafer clinical studies run by Defendants, including but not limited to: "Intravenous Ferric Carboxymaltose (FCM) Versus IV Iron Sucrose or IV Iron Dextran in Treating Iron Deficiency Anemia in Women;" "Trial to Evaluate the Utility of Serum Hepcidin Levels to Predict Response to Oral or IV Iron and to Compare Safety, Effect on Quality of Life, and Resource Utilization of Injectafer vs. Intravenous Standard of Care for the Treatment of Iron Deficiency Anemia (IDA) in an Infusion Center Setting;" A Study to Characterize the Pharmacokinetics and Pharmacodynamics Profile of Intravenous Ferric Carboxymaltose in Pediatric Subjects 1-17 Years Old With Iron Deficiency Anemia (IDA);" and, "IRON Clad: Can Iron Lessen Anemia Due to cancer and chemotherapy: A multicenter, randomized, double-blinded, controlled study to investigate the efficacy and safety of Injectafer."

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

50. Upon information and belief, the Norristown, PA office also was the location at which Luitpold conducted its pharmacovigilance and safety reporting functions for the Injectafer product. Specifically, Luitpold employed its Senior Medical Director, Clinical Quality Assurance,

Senior Clinical Project Manager, and Clinical Research Associate positions, among other pharmacovigilance and safety positions, all in the Norristown, PA office.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

51. Consequently, Luitpold's pharmacovigilance, medical affairs, clinical design, and regulatory functions – either in whole or in substantial part – involving Injectafer all were conducted in the Norristown, PA location.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

52. Pursuant to the licensing and safety agreements between Vifor International and Luitpold, the Vifor Defendants directly participated in the registration and clinical trials, marketing, promotion and marketing sales organization, safety reporting, adverse events arising from clinical trials, and pharmacovigilance obligations for Injectafer, which – either in whole or in substantial part – were conducted or managed in Luitpold's Norristown, PA location.

ANSWER: Defendant admits only that (1) it developed ferric carboxymaltose; (2) it licenses the API to ARI for manufacture and use in the United States by ARI as "Injectafer;" (3) ARI is and only ever has been the sole NDA holder for Injectafer in the United States, and is responsible for compliance with the FDA's regulatory requirements; and (4) the responsibilities of Defendant Vifor International with respect to licensing the API to ARI are formally set forth in the Master Licensing Agreement and the Safety Data Exchange Agreement, which speak for themselves. Defendant denies the remaining allegations as to it in this paragraph, and otherwise

lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and, therefore, denies them.

53. Additionally, the Vifor Defendants, by and through the Vifor Affiliates including, but not limited to, Relypsa, and in conjunction with American Regent, are engaged in the design, manufacture, distribution, marketing, promotion, pharmacovigilance, and/or sale of Injectafer, which – either in whole or in substantial part – were conducted or managed in Luitpold's Norristown, PA location.

ANSWER: Denied.

54. All other Defendants, either as subsidiary, parent, or licensing partner to Luitpold and American Regent, similarly engaged in the aforementioned development, testing, pharmacovigilance, and safety reporting functions for the Injectafer product in the Commonwealth of Pennsylvania. Injectafer was also specifically promoted, marketed, and sold throughout the Commonwealth.

ANSWER: As to entities other than Defendant, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

55. Defendants regularly conduct substantial business within the Eastern District of Pennsylvania.

ANSWER: Defendant denies the allegations in this paragraph as to itself. As to entities other than Defendant Vifor International, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

56. Injectafer is marketed, promoted, distributed, and sold to hospitals, medical facilities, infusion centers, home health care agencies, and consumers in the Philadelphia region within the Eastern District of Pennsylvania.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

57. Venue is proper in the Eastern District of Pennsylvania because Defendants American Regent and Luitpold operate an office out of Norristown, Pennsylvania. See 28 U.S.C.S. § 1391(b)(1)&(2).

ANSWER: Defendant does not contest venue in this Court. As to entities other than Defendant Vifor International, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

58. Venue is also proper in the Eastern District because substantial, specific conduct by the Luitpold Defendant, the American Regent Defendant, and the Vifor Defendants that gave rise to this claim including the design, creation, testing, labeling, development, pharmacovigilance, and sale of Injectafer originated and occurred in Defendants' Philadelphia region office. *See* 28 U.S.C.S. § 1391(b)(2).

ANSWER: Defendant denies the allegations in this paragraph; however, Defendant does not contest venue in this Court. As to entities other than Defendant Vifor International, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

INTRODUCTION AND NATURE OF CASE

59. Injectafer (compound: ferric carboxymaltose) is an iron replacement injection medication manufactured by Defendants indicated "for the treatment of iron deficiency anemia (IDA) in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron, and in adult patients with non-dialysis dependent chronic kidney disease."

ANSWER: Defendant admits only that (1) it developed ferric carboxymaltose; (2) it licenses the API to ARI for manufacture and use in the United States by ARI as "Injectafer;" (3) ARI is and only ever has been the sole NDA holder for Injectafer in the United States, and is responsible for compliance with the FDA's regulatory requirements; and (4) the responsibilities of Defendant Vifor International with respect to the licensing of the API to ARI are formally set forth in the Master Licensing Agreement, which speaks for itself. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and, therefore, denies them.

60. Injectafer entered the United States market in 2013, brought to market by Luitpold Defendants and American Regent Defendants, at the direction and under the control of their parent, the Daiichi Sankyo Defendants. Prior to 2013, the compound "ferric carboxymaltose" was available on the European and other markets under the brand name of Ferinject. Ferinject was designed, manufactured, promoted, and sold by the Vifor Defendants, by and through Vifor International. Defendant Vifor International licensed and continues to license ferric carboxymaltose to all other Defendants who in turn have designed, manufactured, and sold the product in the United States. The Vifor Defendants provide support to American Regent and DSI on the design, manufacture, distribution, marketing, promotion, pharmacovigilance, and/or sale of Injectafer in the United States.

ANSWER: Defendant admits only that (1) it developed ferric carboxymaltose; (2) it designs, manufactures and sells Ferinject in Europe; (3) it licenses the API to ARI for manufacture and use in the United States by ARI as "Injectafer;" (4) ARI is and only ever has been the sole NDA holder for Injectafer in the United States, and is responsible for compliance with the FDA's regulatory requirements; and (5) the responsibilities of Defendant Vifor International with respect to licensing the API to ARI are formally set forth in the Master Licensing Agreement, which speaks for itself. Defendant otherwise denies the allegations in this paragraph.

61. Iron deficiency anemia (hereinafter "IDA") is, put simply, insufficient levels of iron in an individual's body. Iron is a mineral that is essential for the body to produce a healthy amount of red blood cells. Red blood cells work to carry oxygen throughout the body to tissues and organs. Normally, people ingest iron from the foods they eat. When people have poor nutrition or poor absorption of food, this can lead to a shortage of iron and in turn a shortage of red blood cells. When the body does not have enough red blood cells, it is hard to maintain good health.

ANSWER: Defendant admits that iron deficiency anemia ("IDA") is a condition that is, among other things, associated with an insufficient level of iron in an individual's body. The description of IDA in this paragraph is otherwise incomplete and thus Defendant otherwise denies the allegations in this paragraph.

62. For years, IDA was treated with oral iron supplements. The pharmaceutical industry recently began to develop and introduce intravenous iron supplements for those unwilling or unable to take oral iron supplements. Injectafer is a member of the class of intravenous iron products available in the United States.

ANSWER: Defendant admits that IDA is often treated with oral iron supplements. Defendant further admits that, for many patients, oral iron supplements are not options for a variety of reasons, and certain intravenous options have been developed to provide an alternative. Defendant otherwise lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

63. Injectafer is to be administered intravenously in two doses separated by at least 7 days. Each dose should be for 750 mg, for a total cumulative dose of 1500 mg of iron per course.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

64. Injectafer is one of several products available for intravenous iron, but the only product available in the United States formulated with the unique ferric carboxymaltose (hereinafter "FCM") compound.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

65. Unlike the other intravenous iron products available, FCM causes a condition called "Severe Hypophosphatemia" (hereinafter "Severe HPP") and potentially "persistent hypophosphatemia" (hereinafter "Persistent HPP") after use, the condition suffered by Plaintiff in this lawsuit that caused a number of other injuries to be specific in the below sections.

ANSWER: Denied.

66. Hypophosphatemia (hereinafter "HPP") is defined as an electrolyte disturbance in which blood tests reveal that there is an abnormally low level of phosphate in the patient's blood. Phosphorous, or serum phosphate, is critically important and vital to several of the body's

physiological processes. Phosphorous helps with bone growth, energy storage, and nerve and muscle production.

ANSWER: Defendant admits that hypophosphatemia is a condition in which a patient's serum phosphate concentration is below normal. The description of the role of phosphorous in this paragraph is incomplete and thus Defendant denies the remaining allegations in this paragraph.

67. There are several levels of hypophosphatemia, including mild, moderate, and severe. Agreed upon serum phosphate measurements for each level may vary, but typically the measurements break down as: 2.5 – 4.5 mg/dl (normal range); 2.0 – 2.5 mg/dl serum phosphate (mild hypophosphatemia); 1.0 – 2.0 mg/dl (moderate hypophosphatemia); and less than 1.0 mg/dl (severe hypophosphatemia). Severe HPP has also been identified in literature as levels less than 1.5 mg/dl or 1.3 mg/dl.

ANSWER: Defendant admits only that clinicians and researchers define various levels of hypophosphatemia in various ways. Defendant otherwise denies the allegations in this paragraph.

68. Additionally, there is a condition that has been coined as "persistent hypophosphatemia" in which an individual can suffer from hypophosphatemia or severe hypophosphatemia for a sustained period of time.

ANSWER: Defendant admits that the phrase "persistent hypophosphatemia" has been used by clinicians to describe various conditions but denies that it has an accepted definition. Defendant otherwise denies the allegations in this paragraph.

69. There are clinically significant differences between mild hypophosphatemia (2.0 – 2.5 mg/dl) and severe hypophosphatemia (less than 1.5, 1.3, or 1.0 mg/dl). While moderate HPP

can occur without symptomatology or injury, Severe HPP is a dangerous diagnosis that carries with it muscle weakening, fatigue (potentially severe), severe nausea, and can also lead to serious medical complications including osteomalacia, arrhythmias, cardiac arrest, respiratory failure, and/or potentially rhabdomyolysis.

ANSWER: Defendant admits that the extent of a reduction in phosphorous levels in hypophosphatemia can potentially have clinical relevance. Defendant otherwise denies the allegations in this paragraph.

70. The dangers of Severe HPP are not just brought on by the extremely low levels of one's serum phosphate, but also the duration (or prolonged period) of the severe hypophosphatemia.

ANSWER: Defendant admits that the duration of a reduction in phosphorous levels in hypophosphatemia can potentially have clinical relevance. Defendant otherwise denies the allegations in this paragraph.

71. Defendants have known for years, even before the pursuit of a New Drug Application (NDA) for Injectafer, that ferric carboxymaltose – and by extension, Injectafer – causes Severe HPP.

ANSWER: Denied.

72. During ferric carboxymaltose's presence on the European and United States markets, dozens of case reports and important pieces of medical literature emerged revealing the dangers of Severe HPP and linked the ferric carboxymaltose compound to Severe HPP.

ANSWER: Denied.

73. This includes, but is not limited to, studies which have identified the following findings of which Defendants were on notice:

(a) An increasing number of case reports and case series that suggest that some intravenous-iron patients develop severe and symptomatic hypophosphatemia. Diagnosis of iron-induced hypophosphatemia requires clinical suspicion, with treatment guided by the severity of hypophosphatemia;

(b) A comparison between ferric carboxymaltose (Injectafer) and another iron intravenous drug, iron isomaltoside (Monofer) found: "[t]he single most important risk factor for the development of hypophosphatemia appears to be the choice of intravenous iron preparations, **where [ferric carboxymaltose] was associated with a 20-fold higher risk than [iron isomaltoside] and all 18 cases of severe and life-threatening hypophosphatemia developed after administration of [ferric carboxymaltose].**" Moreover, the "prevalence of hypophosphatemia increased from 11% to 32.1% after treatment with [any] intravenous iron." **However, "[t]he hypophosphatemia risk was greater after [ferric carboxymaltose] (45.5%). And cases of "[s]evere hypophosphatemia occurred exclusively after [ferric carboxymaltose] (32.7%)." In conclusion, "[t]reatement with [ferric carboxymaltose] is associated with a high risk of developing severe and prolonged hypophosphatemia and should therefore be monitored";**

(c) A separate comparison of ferric carboxymaltose to another intravenous iron drug, isomaltoside 1000 (Monofer) found significantly more HPP events when ferric carboxymaltose was administered to the patient at a rate of 64-9 (64 patients treated with ferric carboxymaltose contracted HPP and only 9 treated with isomaltoside 1000 contracted HPP). The study found that

HPP "occurred in up to 50% of patients who received [ferric carboxymaltose]" **and also found cases of severe HPP only with ferric carboxymaltose administration**;

(d) Yet another study had the goal of assessing "the prevalence, duration, and potential consequences of hypophosphatemia after iron injection." Of the group of 78 patients treated with ferric carboxymaltose, **51% developed HPP, including 13% developing severe HPP**. Of those 78 patients "the initial mean phosphate level was 1.08 mmol/L and it decreased to 0.82 mmol/L following the iron administration. **"Hypophosphatemia severity correlated with the dose of [ferric carboxymaltose]." In conclusion, "[h]ypophosphatemia is frequent after parenteral [ferric carboxymaltose] injection and may have clinical consequences"**;

(e) More recently, a comparison between Injectafer and ferumoxytol (Feraheme) found that 58.8% of Injectafer users versus only .9% of Feraheme users had severe hypophosphatemia (*measured in this study as levels under 2.0 mg/dl*); 10% of Injectafer users versus 0% of Feraheme users had extreme hypophosphatemia (*measured in this study as levels below 1.3 mg/dl*); and, 29.1% of Injectafer users versus 0% of Feraheme users continued to have persistence of severe hypophosphatemia at the end of the five-week study period.

ANSWER: Denied. As Plaintiff has failed to provide citations to the studies purported to be summarized in subparagraphs (a) through (e), Defendant lacks knowledge or information sufficient to form a belief about the truth of the

allegations in this paragraph and, therefore, denies them. To the extent such studies exist as alleged, Defendant denies the characterization of each and every one, as each speaks for itself.

74. In addition to the aforementioned reports and literature, Luitpold had knowledge of the link between Injectafer and Severe HPP from its own clinical studies, some of which it never warned the general public via its labeling.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

75. Most recently, in February 2020, a comparison between ferric carboxymaltose (Injectafer) and iron isomaltoside (Monofer) published in the Journal of the American Medical Association (JAMA) found that in one trial (Trial A), the incidence of hypophosphatemia with Monofer was only 7.9% compared with 75% in Injectafer patients; in the other trial (Trial B), the incidence of hypophosphatemia with Monofer was only 8.1% compared with 73.7% in Injectafer patients; **severe hypophosphatemia was not observed in Monofer patients but occurred in 11.3% of Injectafer patients**; and, "**even a single course of Injectafer may adversely affect a person's skeleton which may help explain why repeated dosing of ferric carboxymaltose has been associated with osteomalacia and bone fractures**."

ANSWER: Denied. Defendant denies the characterization of the study purported to be summarized, which speaks for itself.

76. An original New Drug Application (NDA) submitted by Luitpold to Food and Drug Administration (FDA) in July 2006 received a non-approvable letter in response due to clinical safety concerns. An additional NDA application for Injectafer was submitted in September 2007 and again received a non-approval letter due to clinical safety concerns. Among the safety concerns

that halted approval was "**clinically important hypophosphatemia.**" "Clinically important hypophosphatemia" never made its way onto the Injectafer labeling, even after being identified as a cause of earlier application denial.

ANSWER: Defendant admits only that ARI is and has only ever been the sole NDA holder for Injectafer with the FDA and is responsible for compliance with the FDA's regulatory requirements, and that the Injectafer labeling speaks for itself. Defendant otherwise lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

77. Despite FDA's own assessment that Injectafer caused "clinically important hypophosphatemia" and the multiple reports, adverse event reports, and published studies linking Injectafer to Severe HPP, Luitpold brought Injectafer to the United States market in 2013 without any adequate warnings on the product labeling or to the medical community.

ANSWER: Defendant admits only that ARI is and has only ever been the sole NDA holder for Injectafer with the FDA and is responsible for compliance with the FDA's regulatory requirements, and that the Injectafer labeling speaks for itself. Defendant otherwise denies the allegations in this paragraph.

78. Injectafer's label omits, and has at all relevant times since its introduction into the United States market, any reference to Severe HPP or "clinically important hypophosphatemia." The labeling makes no attempt to inform the user and medical community of the clinical differences between the varying levels of hypophosphatemia. At the time of Plaintiff's prescription, the labeling did not inform the user or medical community how to monitor serum

phosphorous levels so as to be on alert for severely decreasing levels that may result in Severe HPP or additional injury.

ANSWER: Defendant admits only that ARI is and has only ever been the sole NDA holder for Injectafer with the FDA and is responsible for compliance with the FDA's regulatory requirements, and that the Injectafer labeling speaks for itself. Defendant otherwise denies the allegations in this paragraph.

79. At the time of Plaintiff's prescription, the label only made passing references to the potential occurrence of hypophosphatemia and **no reference at all to Severe HPP**. Inadequate to sufficiently warn the user and medical community, hypophosphatemia (not qualified as moderate or Severe) was not listed in the "Warnings or Precautions" section or in a prominently placed "Black Box" warning, but instead was merely listed as an "Adverse Reaction" occurring in greater than 2% of users.

ANSWER: Defendant admits only that ARI is and has only ever been the sole NDA holder for Injectafer with the FDA and is responsible for compliance with the FDA's regulatory requirements, and that the Injectafer labeling speaks for itself. Defendant otherwise denies the allegations in this paragraph.

80. When the label did reference the potential adverse reaction of regular hypophosphatemia, it significantly downplayed the risk and potential for injury thus confusing and nullifying the nature of any potential warning:

(a) From introduction into the market in July 2013 through January 2018, the "Patient Information" leaflet section of the labeling refers to "**asymptomatic** reductions in blood phosphorous";

(b) In January 2018, Defendants removed the "asymptomatic" reference in the Patient Information leaflet and simply listed "low levels of phosphorous in your blood," still without reference to Severe HPP or any explanation as to the clinical significance of low levels of blood phosphorous. Additionally, no portions of the Prescribing Information were adjusted to reflect a potential increase in warning as to the symptoms and injuries that can accompany even a diagnosis of mild or moderate hypophosphatemia;

(c) In the "Adverse Reactions in Clinical Trials" section of the labeling, Defendants refer only to "*transient* decreases in laboratory blood phosphorous levels (< 2 mg/dl)";

ANSWER: Defendant admits only that ARI is and has only ever been the sole NDA holder for Injectafer with the FDA and is responsible for compliance with the FDA's regulatory requirements, and that the Injectafer labeling speaks for itself. Defendant otherwise denies the allegations in this paragraph, including as to each subparagraph.

81. The aforementioned references to "transient" or "asymptomatic" reductions of blood phosphorous grossly mischaracterize the known, sharp decrease in blood phosphorous that can result in Severe HPP and persist over a time period of weeks or months, carrying with it dangerous, prolonged, and potentially permanent injuries. The injuries and conditions caused by Severe HPP can have permanent effects, none of which are conveyed to the medical community via Injectafer's labeling.

ANSWER: Defendant admits only that ARI is and has only ever been the sole NDA holder for Injectafer with the FDA and is responsible for compliance with

the FDA's regulatory requirements, and that the Injectafer labeling speaks for itself. Defendant otherwise denies the allegations in this paragraph.

82. The labeling made no reference to the following clinical conditions associated with Severe HPP: rhabdomyolysis, cardiac arrest, cardiac arrhythmia, or respiratory failure. The labeling only made passing, inadequate reference in the Post-marketing experience to hypophosphatemic osteomalacia that was reported in *one* individual.

ANSWER: Defendant admits only that ARI is and has only ever been the sole NDA holder for Injectafer with the FDA and is responsible for compliance with the FDA's regulatory requirements, and that the Injectafer labeling speaks for itself. Defendant otherwise denies the allegations in this paragraph.

83. In April 2018 or thereabouts, Defendants removed the reference to "asymptomatic" reductions in blood phosphorous from the labeling.

ANSWER: Defendant admits only that ARI is and has only ever been the sole NDA holder for Injectafer with the FDA and is responsible for compliance with the FDA's regulatory requirements, and that the Injectafer labeling speaks for itself. Defendant otherwise denies the allegations in this paragraph.

84. Most recently, in February 2020, the FDA approved revised labeling for Injectafer that includes the following changes allegedly related to hypophosphatemia:

(a) Addition of Section 2.3, entitled "Repeat Treatment Monitoring Safety Assessment," under "Dosage and Administration" that states: "Injectafer treatment may be repeated if iron deficiency anemia reoccurs. **Monitor serum phosphate levels in patients at risk for low serum phosphate who**

require a repeat course of treatment [see Warnings and Precautions (5.2)]";

(b) Addition of Section 5.2, entitled "Symptomatic Hypophosphatemia," under "Warnings and Precautions" that states: "Symptomatic hypophosphatemia requiring clinical intervention has been reported in patients at risk of low serum phosphate in the postmarketing setting. These cases have occurred mostly after repeated exposure to Injectafer in patients with no reported history of renal impairment. Possible risk factors for hypophosphatemia include a history of gastrointestinal disorders associated with malabsorption of fat-soluble vitamins or phosphate, concurrent or prior use of medications that affect proximal renal tubular function, hyperparathyroidism, vitamin D deficiency and malnutrition. In most cases, hypophosphatemia resolved within three months. Monitor serum phosphate levels in patients at risk for low serum phosphate who require a repeat course of treatment. [see Dosage and Administration (2.3)]";

(c) In Section 6, "Adverse Reactions," Hypophosphatemia was added as a bulleted adverse reaction;

(d) In Section 6.2, "Postmarketing Experience," the following was added: "Metabolism and nutrition disorders: Hypophosphatemia";

(e) In Section 10, "Overdosage", the following was added: "A patient who received Injectafer 18,000 mg over 6 months developed hemosiderosis with multiple joint disorder, walking disability, and asthenia."

ANSWER: Defendant admits only that ARI is and has only ever been the sole NDA holder for Injectafer with the FDA and is responsible for compliance with the FDA's regulatory requirements, and that the Injectafer labeling speaks for itself. Defendant otherwise denies the allegations in this paragraph, including as to each subparagraph.

85. Failure to warn of Severe HPP, along with the injuries it can cause – osteomalacia, rhabdomyolysis, cardiac arrest, cardiac arrhythmia, or respiratory failure – given their clinical significance and Defendants' knowledge of the frequency at which they occur in Injectafer users, is a complete derogation of Defendants' responsibilities to properly warn of Injectafer's known dangers in violation of all relevant state and federal laws.

ANSWER: Denied.

86. In addition to the omission of any reference to Severe HPP, the labeling also omits any reference in the Clinical Pharmacology section to ferric carboxymaltose's known effect on the FGF23 hormone, which in turn is associated with a decrease in blood phosphorous.

ANSWER: Defendant admits only that ARI is and has only ever been the sole NDA holder for Injectafer with the FDA and is responsible for compliance with the FDA's regulatory requirements, and that the Injectafer labeling speaks for itself. Defendant otherwise denies the allegations in this paragraph.

87. Defendants have long known that ferric carboxymaltose increases the levels of the hormone fibroblast growth factor 23 ("FGF23") at a rate far greater than any other iron drug. Additionally, Defendants have long known that increases in FGF23 can induce hypophosphatemia, possibly through reduction of phosphate reabsorption in the body. Despite these accepted and known facts, Defendants at no place in the Injectafer labeling, nor via any other means of

communication to the medical community, notified potential users and physicians of Injectafer's propensity to increase FGF23 levels far beyond the capacity of any other iron drug. Defendants have been aware of these risks since and before Injectafer's entrance into the United States market.

ANSWER: Defendant admits only that ARI is and has only ever been the sole NDA holder for Injectafer with the FDA and is responsible for compliance with the FDA's regulatory requirements, and that the Injectafer labeling speaks for itself. Defendant otherwise denies the allegations in this paragraph.

88. Defendants, as the entities responsible for the Injectafer product and labeling, had a duty to warn potential users of Injectafer's known risks of Severe HPP, as well as the injuries that can result from Severe HPP, and also Injectafer's known propensity to increase FGF23 which in turn can cause both acute and potentially prolonged Severe HPP.

ANSWER: Denied.

89. Defendants at no times have attempted to warn users of these risks and have therefore violated their duties to warn and not misrepresent the benefits of a drug.

ANSWER: Denied.

90. Defendants also have a duty to explain to the medical community how to properly investigate and monitor a sharp drop in phosphorous levels. Defendants at no time have provided such warnings.

ANSWER: Denied.

91. Defendants additionally have a duty to not manufacture, market, and sell a product with so unreasonably dangerous that its potential harms far outweigh any potential benefits. Defendants have failed their duty to ensure safe, well-tested, well-monitored, and properly labeled products are entered into the pharmaceutical market.

ANSWER: Denied.

PLAINTIFF'S USE OF INJECTAFER

92. Plaintiff incorporates by reference the factual portion of this Complaint as if fully set forth herein and additionally, or in the alternative, if same be necessary, allege as follows.

ANSWER: Defendant incorporates by reference its responses to paragraphs 1 through 91 above.

93. Plaintiff, Katherine Crockett, was a resident of Philadelphia, PA during all times relevant to this litigation and is now a resident of New York, NY.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

94. On May 3, 2017, Plaintiff was prescribed Injectafer iron injection for treatment of her IDA at the Mayo Clinic in Rochester, Minnesota.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

95. Plaintiff received the first injection at the Mayo Clinic on May 5, 2017. Plaintiff received her second injection in Philadelphia, PA on May 16, 2017.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

96. Following Plaintiff's first Injectafer injection, her blood phosphorous levels sharply dropped. At one measurement on May 11, 2017, her blood phosphorous dropped to 1.6 mg/dl. Following her second Injectafer administration, laboratory tests on May 19, 2017 revealed a blood phosphorous level in the Severe Hypophosphatemia range of 1.2 mg/dl. These tests do not necessarily represent the lowest levels of Plaintiff's blood phosphorous following the Injectafer administration.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

97. Plaintiff was subsequently diagnosed with Severe Hypophosphatemia and, as a result, suffered from multiple hospitalizations, severe nausea, severe weakness and pain, and severe and constant fatigue. Plaintiff was additionally diagnosed with renal phosphate wasting that Plaintiff alleges was caused by Injectafer. As a result of Plaintiff's severe and ongoing injuries, Plaintiff had to take a leave of absence from her place of employment and was only able to return after several months on limited duties.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

98. As a result of her use of Injectafer, Plaintiff has suffered, and will likely suffer in the future, severe and permanent injuries and damages. Plaintiff's severe and permanent injuries impair her daily activities.

ANSWER: Denied.

99. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of material facts known by the Defendants when they had a duty to disclose those facts. The Defendants' purposeful and fraudulent acts of concealment have keep Plaintiff ignorant of vital information essential to the pursuit of Plaintiff's claims, without any fault or lack of diligence on Plaintiff's part, for the purpose of obtaining delay on Plaintiff's filing of their causes of action. The Defendants' fraudulent concealment did result in such delay.

ANSWER: Denied.

100. Defendants are estopped from relying on the statute of limitations defense because Defendants failed to timely disclose, among other things, facts evidencing the defective and

unreasonably dangerous nature of Injectafer, as well as information related to Injectafer's known ability to cause Plaintiff's injury

ANSWER: Denied.

101. As pled below, Plaintiff seeks the application of the law of the forum state, Pennsylvania, which is also home to Defendant Luitpold. However, should this Court determine in a "choice of law" analysis that another state's law should apply to this matter, Plaintiff reserves the right to recover under the laws of that state, as pled below.

ANSWER: Defendant admits only that Plaintiff seeks relief as stated, denies that Plaintiff is entitled to any relief under any State's law, and otherwise denies the allegations in this paragraph.

COUNT I – NEGLIGENCE
(The American Regent Defendants, The Daiichi Sankyo Defendants, and The Vifor Defendants)

102. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

ANSWER: Defendant incorporates by reference its responses to paragraphs 1 through 101 above.

103. At all times relevant, the Defendants were in the business of designing, developing, testing, manufacturing, labeling, marketing, advertising, promoting, monitoring, selling and/or distributing Injectafer, including the product administered to Plaintiff.

ANSWER: Defendant admits only that it researched, developed, and designed ferric carboxymaltose and it licenses the API to ARI for manufacture and use in the United States by ARI as "Injectafer." As to entities other than Defendant Vifor International, Defendant lacks knowledge or information sufficient to form a

belief about the truth of the allegations in this paragraph and, therefore, denies them. Defendant otherwise denies the allegations as to it in this paragraph.

104. Defendants had a duty to exercise reasonable and ordinary care in the designing, developing, testing, manufacturing, labeling, marketing, advertising, promoting, monitoring, selling and/or distributing of Injectafer so as to avoid exposing others to foreseeable and unreasonable risks of harm.

ANSWER: This paragraph states legal conclusions to which no responsive pleading is required. For a further response, Defendant admits only that ARI is and has only ever been the sole NDA holder for Injectafer with the FDA and is responsible for compliance with the FDA's regulatory requirements. Defendant denies that it breached any duty and otherwise denies the allegations in this paragraph.

105. Defendants breached their duty of care to the Plaintiff and her physicians, in the testing, monitoring, and pharmacovigilance of Injectafer.

ANSWER: Denied.

106. Defendants knew or reasonably should have known that Injectafer was dangerous or likely to be dangerous when used in its intended or reasonably foreseeable manner.

ANSWER: Denied.

107. At the time of the manufacture and sale of Injectafer, Defendants knew or should have known that Injectafer was designed in such a manner so as to cause Severe Hypophosphatemia and the additional injuries that are known to stem from that diagnosis.

ANSWER: Denied.

108. At the time of the manufacturer and sale of Injectafer, Defendants knew or should have known that Injectafer caused a sharp increase in the hormone FGF23 which in turn is associated with a decrease in blood phosphorous and a host of other sequelae not evident in other iron injection formulations.

ANSWER: Denied.

109. At the time of the manufacturer and sale of Injectafer, Defendants knew or should have known that using Injectafer for its intended use to treat IDA or for other indicated or unindicated conditions promoted by Defendants created a significant risk of a patient suffering severe injuries, including but not limited to diagnosis of Severe Hypophosphatemia and the injuries that result consequence to severely low levels of blood phosphorous.

ANSWER: Denied.

110. Defendants knew or reasonably should have known that the consumers of Injectafer would not realize the danger associated with administration of the drug for its intended use and/or in a reasonably foreseeable manner.

ANSWER: Denied.

111. Defendants breached their duty to exercise reasonable and prudent care in the testing, monitoring, and pharmacovigilance, among others, the following ways:

(a) Failing to perform reasonable pre-and post-market testing of the product to investigate Injectafer's (ferric carboxymaltose) propensity to cause Severe Hypophosphatemia;

(b) Failing to adequately monitor the adverse events related to Injectafer (ferric carboxymaltose) known to Defendants from published case reports, studies, and reports submitted to Defendants and FDA;

(c) Failing to establish and maintain an adequate post-marketing surveillance program for Injectafer (ferric carboxymaltose) given Defendants' knowledge of link between product and Severe Hypophosphatemia from experiences with ferric carboxymaltose in non-United States markets.

ANSWER: Denied, including as to each subparagraph.

112. A reasonable manufacturer, designer, distributor, promotor, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

ANSWER: Denied.

113. As a direct and proximate result of the Defendants' negligent testing, monitoring, and pharmacovigilance of Injectafer (ferric carboxymaltose), Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

ANSWER: Denied.

114. The aforementioned negligence and wrongs done by the Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary (or, punitive) damages, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included material representations that were false, with Defendants knowing that they was false or with reckless

disregard as to the truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff .

ANSWER: Denied.

115. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania common law.

ANSWER: Denied.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of $75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

ANSWER: Defendant requests that judgment be entered in its favor and against Plaintiff, and that this Court dismiss the Complaint with prejudice and grant Defendant its attorney's fees and costs and such other and further relief as the Court deems to be just and appropriate.

COUNT II – NEGLIGENT FAILURE TO WARN
(The American Regent Defendants, The Daiichi Sankyo Defendants, and The Vifor Defendants)

116. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

ANSWER: Defendant incorporates by reference its responses to paragraphs 1 through 115 above.

117. Defendants had a duty to exercise reasonable care and comply with existing standards of care in the marketing, promotion, labeling, packaging, and sale of Injectafer.

ANSWER: This paragraph states legal conclusions to which no responsive pleading is required. For a further response, Defendant admits only that ARI is

and has only ever been the sole NDA holder for Injectafer with the FDA and is responsible for compliance with the FDA's regulatory requirements. Defendant denies that it breached any duty and otherwise denies the allegations in this paragraph.

118. Defendants failed to exercise reasonable care and failed to comply with existing standards of care in the marketing, promotion, labeling, packaging, and sale of Injectafer. Defendants knew or should have known that using Injectafer as instructed in the labeling created an unreasonable risk of harm.

ANSWER: Denied.

119. Defendants, its agents, servants, partners, and/or employees, failed to exercise reasonable care and failed to comply with existing standards of care in the following acts and/or omissions, among others:

(a) Promoting and marketing Injectafer while knowing at the time of its NDA approval and prior that Injectafer caused Severe Hypophosphatemia;

(b) Failing to warn in all Injectafer labeling that Injectafer and ferric carboxymaltose caused Severe Hypophosphatemia;

(c) Failing to warn in all Injectafer promotions, Continuing Medical Education (CME), symposia, luncheons, seminars, advertising, publications, and other means of communication to medical community and targeted patient populations that Injectafer caused Severe Hypophosphatemia;

(d) Failing to warn of the true incident rates of Severe Hypophosphatemia and Hypophosphatemia from all clinical studies completed by Defendants;

(e) Failing to warn of the accurate and known long-term effects of hypophosphatemia and Severe Hypophosphatemia;

(f) Failing to warn of the differences in severity between mild, moderate, and severe hypophosphatemia;

(g) Failing to warn physicians and users of need to monitor serum phosphorous levels after administration of Injectafer;

(h) Failing to warn physicians and consumers of need to supplement phosphorous levels after administration of Injectafer;

(i) Failing to instruct physician and consumers of available treatments for injuries, including but not limited to Severe Hypophosphatemia, caused by Injectafer; and,

(j) Failing to disclose their knowledge that Injectafer was known to increase the hormone FGF23 which was known to be associated with a decrease in levels of serum phosphate.

ANSWER: Denied, including as to each subparagraph.

120. Defendants' failure to warn of the above was the proximate cause of Plaintiff's injuries, harm, and economic loss, which Plaintiff continues to suffer.

ANSWER: Denied.

121. The aforementioned negligence and wrongs done by the Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary (or, punitive) damages, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiff; or when

viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included material representations that were false, with Defendants knowing that they was false or with reckless disregard as to the truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff .

ANSWER: Denied.

122. Defendants are liable in tort to Plaintiff for their negligent failure to warn under Pennsylvania common law.

ANSWER: Denied.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of $75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues as triable as a matter of right.

ANSWER: Defendant requests that judgment be entered in its favor and against Plaintiff, and that this Court dismiss the Complaint with prejudice and grant Defendant its attorney's fees and costs and such other and further relief as the Court deems to be just and appropriate.

COUNT III – NEGLIGENT DESIGN DEFECT
(The American Regent Defendants, The Daiichi Sankyo Defendants, and The Vifor Defendants)

123. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

ANSWER: Defendant incorporates by reference its responses to paragraphs 1 through 122 above.

124. Defendants are liable to Plaintiff for the injuries and damages sustained by Plaintiff due to their negligent design and/or formulation of Injectafer.

ANSWER: Denied.

125. At all relevant times to this lawsuit, Defendants owed a duty to consumers including Plaintiff and her health care providers, to assess, manage, and communicate the risks, dangers, and adverse effects of Injectafer. The Defendants' duties included, but were not limited to, carefully and properly designing, testing, studying, and manufacturing Injectafer.

ANSWER: This paragraph states legal conclusions to which no responsive pleading is required. For a further response, Defendant admits only that ARI is and has only ever been the sole NDA holder for Injectafer with the FDA and is responsible for compliance with the FDA's regulatory requirements. Defendant denies that it breached any duty and otherwise denies the allegations in this paragraph.

126. The Defendants negligently and carelessly breached the above-described duties to Plaintiff by, among other acts and omissions, negligently and carelessly:

(a) Failing to use ordinary care in designing, testing, and manufacturing Injectafer;

(b) Failing to design Injectafer as to properly minimize the effects on the hormone FGF23 that was known when increased to in turn decrease serum phosphorous;

(c) Failing to counteract in the design the known effects of ferric carboxymaltose that result in an increase in FGF23 and decrease of serum phosphorus;

(d) Designing a product with excessive amounts of iron where the benefits of additional iron were greatly outweighed by the risks of excessive iron injected into the body;

(e) Designing a product without taking into consideration the proper dosage and necessary break in time between administrations;

(f) Utilizing false and misleading claims, including ghost-writing, in advertisements, professional meetings, medical journal articles, advisory meetings, promotional speaking, CMEs, leave-behinds at prescriber offices, detailing, and by other methods and materials in the design and formulation of Injectafer.

ANSWER: Denied, including as to each subparagraph.

127. The Injectafer that was manufactured, distributed, sold and/or supplied by Defendants was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, the foreseeable risks exceeded the benefits associated with the design or formulation.

ANSWER: Denied.

128. The Injectafer manufactured, distributed, sold and/or supplied by Defendants was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, it was unreasonably dangerous, it was unreasonably dangerous and

more dangerous than an ordinary consumer would expect and more dangerous than other iron injection drugs.

ANSWER: Denied.

129. Despite Defendants' knowledge of the foreseeable risks and unreasonably dangerous nature of Injectafer when the product at all times relevant, Defendants brought the product to market and continued to market the drug when there were safer alternatives available and in actual use in the United States.

ANSWER: Denied.

130. The aforementioned negligence and wrongs done by the Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary (or, punitive) damages, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included material representations that were false, with Defendants knowing that they was false or with reckless disregard as to the truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff .

ANSWER: Denied.

131. As a direct and proximate result of the Defendants' negligent acts and design of Injectafer, Plaintiff suffered injuries and damages as set forth in this Complaint.

ANSWER: Denied.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of $75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues as triable as a matter of right.

ANSWER: Defendant requests that judgment be entered in its favor and against Plaintiff, and that this Court dismiss the Complaint with prejudice and grant Defendant its attorney's fees and costs and such other and further relief as the Court deems to be just and appropriate.

COUNT IV – NEGLIGENT MISREPRESENTATION
(The American Regent Defendants, The Daiichi Sankyo Defendants, and The Vifor Defendants)

132. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

ANSWER: Defendant incorporates by reference its responses to paragraphs 1 through 131 above.

133. At all relevant times, Defendants negligently provided Plaintiff, her healthcare providers, and the general medical community with false or incorrect information, or omitted or failed to disclose material information concerning Injectafer, including, but not limited to, misrepresentations regarding the safety and known risks of Injectafer.

ANSWER: Denied.

134. The information distributed by the Defendants to the public, the medical community, Plaintiff and her healthcare providers, including advertising campaigns, labeling materials, print advertisements, commercial media, was false and misleading and contained omissions and concealment of truth about the dangers of Injectafer.

ANSWER: Denied.

135. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff and Plaintiffs' health care providers; to falsely assure them of the quality of Injectafer and induce the public and medical community, including Plaintiff and her healthcare provider to request, recommend, purchase, and prescribe Injectafer.

ANSWER: Denied.

136. The Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, medical device manufacturers, Plaintiff, her healthcare providers and the public, the known risks of Injectafer involving its propensity to cause Severe Hypophosphatemia.

ANSWER: This paragraph states legal conclusions to which no responsive pleading is required. For a further response, Defendant admits only that ARI is and has only ever been the sole NDA holder for Injectafer with the FDA and is responsible for compliance with the FDA's regulatory requirements. Defendant denies that it breached any duty and otherwise denies the allegations in this paragraph.

137. Defendants made continued misrepresentations in the Injectafer labeling, including but not limited to:

(a) Decrease in serum phosphorous are simply "transient";

(b) Decreases in serum phosphorous are "asymptomatic";

(c) Misrepresenting the total number of incidences of low blood phosphorous findings in the multiple clinical studies completed by Defendants;

(d) Misrepresenting the severity of hypophosphatemia associated with Injectafer by failing to warn of Severe Hypophosphatemia while only referencing in passing an adverse effect of hypophosphatemia, which was interpreted by Plaintiff, Plaintiff's treaters, and the medical community to not rise to the level of Severe Hypophosphatemia;

(e) Advertising, promoting, and marketing Injectafer as a safe and superior iron injection drug to the other iron injection drugs on the market that were not known to cause Severe Hypophosphatemia.

ANSWER: Denied, including as to each subparagraph.

138. Defendants have made additional misrepresentations beyond the product labeling by representing Injectafer as a safe and superior intravenous iron product with only minimal risks.

ANSWER: Denied.

139. Defendants misrepresented and overstated the benefits of Injectafer to Plaintiff, Plaintiff's treaters, and the medical community without properly advising of the known risks related to decreases in serum phosphorous.

ANSWER: Denied.

140. In reliance upon the false and negligent misrepresentations and omissions made by the Defendants, Plaintiff and Plaintiff's healthcare providers were induced to, and did use the Injectafer, thereby causing Plaintiff to endure severe and permanent injuries.

ANSWER: Denied.

141. In reliance upon the false and negligent misrepresentations and omissions made by the Defendants, Plaintiff and Plaintiff's healthcare providers were unable to associate the injuries sustained by Plaintiff with her Injectafer use, and therefore unable to provide adequate treatment.

ANSWER: Denied.

142. Defendants knew and had reason to know that the Plaintiff, Plaintiff's healthcare providers, and the general medical community did not have the ability to determine the true facts which were intentionally and/or negligently concealed and misrepresented by the Defendants.

ANSWER: Denied.

143. Plaintiff and her healthcare providers would not have used or prescribed Injectafer had the true facts not been concealed by the Defendants.

ANSWER: Denied.

144. Defendants had sole access to many of the material facts concerning the defective nature of Injectafer and its propensity to cause serious and dangerous side effects.

ANSWER: Denied.

145. At the time Plaintiff was prescribed and administered Injectafer, Plaintiff and her healthcare providers were unaware of Defendants' negligent misrepresentations and omissions.

ANSWER: Denied.

146. The Defendants failed to exercise ordinary care in making representations concerning Injectafer while they were involved in their manufacture, design, sale, testing, quality assurance, quality control, promotion, marketing, labeling, and distribution in interstate commerce, because the Defendants negligently misrepresented Injectafer's high risk of unreasonable and dangerous adverse side effects.

ANSWER: Denied.

147. Plaintiff and Plaintiff's healthcare providers reasonably relied upon the misrepresentations and omissions made by the Defendants where the concealed and

misrepresented facts were critical to understanding the true dangers inherent in the use of the Injectafer.

ANSWER: Denied.

148. Plaintiff and Plaintiff's healthcare providers' reliance on the foregoing misrepresentations and omissions was the direct and proximate cause of Plaintiffs injuries.

ANSWER: Denied.

149. The aforementioned misrepresentations and wrongs done by the Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary (or, punitive) damages, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included material representations that were false, with Defendants knowing that they was false or with reckless disregard as to the truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff .

ANSWER: Denied.

150. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania common law.

ANSWER: Denied.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of $75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues as triable as a matter of right.

ANSWER: Defendant requests that judgment be entered in its favor and against Plaintiff, and that this Court dismiss the Complaint with prejudice and grant Defendant its attorney's fees and costs and such other and further relief as the Court deems to be just and appropriate.

COUNT V – FRAUD
(The American Regent Defendants and The Daiichi Sankyo Defendants)

151. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

ANSWER: Defendant incorporates by reference its responses to paragraphs 1 through 150 above.

152. The Defendants, specifically American Regent, Luitpold, and Daiichi Sankyo, falsely and fraudulently have represented and continue to represent to the medical and healthcare community, Plaintiff and her physicians, and/or the public that Injectafer has been appropriately tested and was found to be safe and effective.

ANSWER: The allegations in this paragraph are not directed toward Defendant, and therefore no response is required. To the extent a response is required, it is denied.

153. The representations made by the Defendants American Regent, Luitpold, and Daiichi Sankyo were, in fact, false. When the Defendants made their representations, they knew and/or had reason to know that those representations were false, and they willfully, wantonly, and

recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of Injectafer.

ANSWER: The allegations in this paragraph are not directed toward Defendant, and therefore no response is required. To the extent a response is required, it is denied.

154. These representations were made by the Defendants American Regent, Luitpold, and Daiichi Sankyo with the intent of defrauding and deceiving the medical community, Plaintiff, and the public, and also inducing the medical community, Plaintiff, Plaintiff's physicians, and/or the public, to recommend, prescribe, dispense, and purchase Injectafer for use as a treatment for Iron Deficiency Anemia (IDA) while concealing the drug's known propensity to cause Severe Hypophosphatemia and the consequent injuries that occur from low levels of blood phosphorous.

ANSWER: The allegations in this paragraph are not directed toward Defendant, and therefore no response is required. To the extent a response is required, it is denied.

155. In representations to Plaintiff and/or to her healthcare providers, including Plaintiff's prescribing physician Dr. Go, the Defendants American Regent, Luitpold, and Daiichi Sankyo fraudulently stated on the Injectafer product labeling in existence at the time Plaintiff was prescribed Injectafer in May 2017, specifically the Injectafer (ferric carboxymaltose) labeling Revised July 2013:

(a) Decreases in serum phosphorous are simply "transient" (Section 6.1);

(b) Decreases in serum phosphorous are "asymptomatic" (Patient Information);

(c) Misrepresenting the total number of incidences of low blood phosphorous findings in the multiple clinical studies completed by Defendants (Section 6.1);

(d) That Injectafer was safe and efficacious for adult Patients regardless of pre-existing conditions related to blood phosphorous disease or deficiency, or FGF23 disease or deficiency.

ANSWER: The allegations in this paragraph are not directed toward Defendant, and therefore no response is required. To the extent a response is required, it is denied, including as to each subparagraph.

156. In representations to Plaintiff and/or to her healthcare providers, including Plaintiff's prescribing physician Dr. Go, the Defendants American Regent, Luitpold, and Daiichi Sankyo fraudulently concealed and intentionally omitted the following material information from the Injectafer product labeling in existence at the time Plaintiff was prescribed Injectafer in May 2017, specifically the Injectafer (ferric carboxymaltose) labeling Revised July 2013:

(a) That Injectafer causes Severe Hypophosphatemia and potentially long-term and permanent injuries that result from low blood phosphorous including but not limited to osteomalacia, rhabdomyolysis, respiratory failure, cardiac arrest, cardiac arrhythmia;

(b) That Injectafer was known to increase the hormone FGF23 which in turn is associated with the decreased of blood phosphorus levels;

(c) That Injectafer was considerably less safe than the other iron supplement and iron injection products on the market given its unique propensity to cause Severe Hypophosphatemia;

(e) That Injectafer was not adequately tested following the Defendants' knowledge that the drug was causing Severe Hypophosphatemia at increased and alarming levels;

(f) That Defendants deliberately failed to follow up on the adverse results from clinical studies and formal and informal reports from physicians and other healthcare providers and either ignored, concealed and/or misrepresented those findings;

(g) That there is a clinically important difference between mild or moderate hypophosphatemia and Severe Hypophosphatemia, the latter of which is a serious harm caused by Injectafer use; and,

(h) That Injectafer was negligently designed as set forth in the Negligent Defective Design Count.

ANSWER: The allegations in this paragraph are not directed toward Defendant, and therefore no response is required. To the extent a response is required, it is denied, including as to each subparagraph.

157. The American Regent, Luitpold, and Daiichi Sankyo Defendants were under a duty to disclose to Plaintiff and her physicians the defective nature of Injectafer, including but not limited to, the risk of Severe Hypophosphatemia and its ability to cause debilitating and/or permanent injuries.

ANSWER: The allegations in this paragraph are not directed toward Defendant, and therefore no response is required. To the extent a response is required, it is denied.

158. The Defendants American Regent, Luitpold, and Daiichi Sankyo had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiff, and/or her physicians.

ANSWER: The allegations in this paragraph are not directed toward Defendant, and therefore no response is required. To the extent a response is required, it is denied.

159. The American Regent, Luitpold, and Daiichi Sankyo Defendants knew or had reason to know that incidences of decreased in blood phosphorous were not temporary, transient, or asymptomatic, as a result of information from case studies, clinical trials, literature, and adverse event reports available to the Defendants at the time of the development and sale of Injectafer, as well as at the time of Plaintiff's Injectafer prescription.

ANSWER: The allegations in this paragraph are not directed toward Defendant, and therefore no response is required. To the extent a response is required, it is denied.

160. The American Regent, Luitpold, and Daiichi Sankyo Defendants knew or had reason to know that Injectafer caused Severe Hypophosphatemia and related conditions as a result of information from case studies, clinical trials, literature, and adverse event reports available to the Defendants at the time of the development and sale of Injectafer, as well as at the time of Plaintiff's Injectafer prescription.

ANSWER: The allegations in this paragraph are not directed toward Defendant, and therefore no response is required. To the extent a response is required, it is denied.

161. The American Regent, Luitpold, and Daiichi Sankyo Defendants' concealment and omissions of material facts concerning the safety of the Injectafer were made purposefully, willfully, wantonly, and/or recklessly to mislead Plaintiff, Plaintiff's physicians, surgeons and healthcare providers and to induce them to purchase, prescribe, and/or use Injectafer.

ANSWER: The allegations in this paragraph are not directed toward Defendant, and therefore no response is required. To the extent a response is required, it is denied.

162. At the time these representations were made by Defendants, and at the time Plaintiff and/or her physicians used Injectafer, Plaintiff and/or her physicians were unaware of the falsehood of these representations.

ANSWER: The allegations in this paragraph are not directed toward Defendant, and therefore no response is required. To the extent a response is required, it is denied.

163. In reliance upon these false representations, Plaintiff was induced to, and did use Injectafer, thereby causing severe, debilitating, and potentially permanent personal injuries and damages to Plaintiff. The Defendants knew or had reason to know that the Plaintiff had no way to determine the truth behind the Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of Injectafer, as described in detail herein.

ANSWER: The allegations in this paragraph are not directed toward Defendant, and therefore no response is required. To the extent a response is required, it is denied.

164. In comporting with the standard of care for prescribing physicians, Plaintiff's prescribing physician relied on the labeling for Injectafer in existence at the May 2017 date of prescription that included the aforementioned fraudulent statements and omissions.

ANSWER: The allegations in this paragraph are not directed toward Defendant, and therefore no response is required. To the extent a response is required, it is denied.

165. These representations made by American Regent, Luitpold, and Daiichi Sankyo were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

ANSWER: The allegations in this paragraph are not directed toward Defendant, and therefore no response is required. To the extent a response is required, it is denied.

166. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations of the Defendants American Regent, Luitpold, and Daiichi Sankyo, nor would Plaintiff with reasonable diligence have discovered the true facts about the Defendant's misrepresentations at the time when Injectafer was prescribed to her.

ANSWER: The allegations in this paragraph are not directed toward Defendant, and therefore no response is required. To the extent a response is required, it is denied.

167. As a proximate result of the Defendants' fraudulent statements and omissions, Plaintiff has been seriously injured, and sustained severe and permanent injury, pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

ANSWER: The allegations in this paragraph are not directed toward Defendant, and therefore no response is required. To the extent a response is required, it is denied.

168. The aforementioned fraudulent statements and omissions and wrongs done by the Defendants were aggravated by the kind of malice and grossly negligent disregard for the rights of others, the public, and Plaintiff, for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary (or, punitive) damages, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included material representations that were false, with Defendants knowing that they was false or with reckless disregard as to the truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff .

ANSWER: The allegations in this paragraph are not directed toward Defendant, and therefore no response is required. To the extent a response is required, it is denied.

169. Defendants are liable in tort to Plaintiff for their fraudulent conduct pursuant to Pennsylvania common law.

ANSWER: The allegations in this paragraph are not directed toward Defendant, and therefore no response is required. To the extent a response is required, it is denied.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of $75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues as triable as a matter of right.

ANSWER: Defendant requests that judgment be entered in its favor and against Plaintiff, and that this Court dismiss the Complaint with prejudice and grant Defendant its attorney's fees and costs and such other and further relief as the Court deems to be just and appropriate

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully demands judgment against all Defendants and each of them, individually, jointly and severally, and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

A) compensatory damages for past, present, and future damages, including, but not limited to, great pain and suffering and emotional distress and anguish, for personal injuries sustained by Plaintiff, health and medical care costs, together with interest and costs as provided by law;

B) for all ascertainable economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;

C) for specific damages according to proof;

D) for Punitive and Exemplary damages according to proof;

E) for pre-judgment interest and post-judgment interest as allowed by law;

F) for reasonable attorneys' fees;

G) for the costs of these proceedings; and

H) for such other and further relief as this Court deems just and proper.

ANSWER: Defendant requests that judgment be entered in its favor and against Plaintiff, and that this Court dismiss the Complaint with prejudice and grant Defendant its attorney's fees and costs and such other and further relief as the Court deems to be just and appropriate. Defendant denies that Plaintiff is entitled to any of the damages or other relief, including attorneys' fees or costs, specified here or at any point in the Complaint.

DEMAND FOR JURY TRIAL

Plaintiff demands a jury trial with regards to all claims.

ANSWER: Defendant admits only that Plaintiff seeks a jury trial, and requests that judgment be entered in its favor and against Plaintiff, and that this Court dismiss the Complaint with prejudice and grant Defendant its attorney's fees and costs and such other and further relief as the Court deems to be just and appropriate.

Defendant denies any and all allegations contained in the Complaint not specifically admitted hereinabove.

AFFIRMATIVE DEFENSES

In further response to the Complaint, Defendant pleads the following Affirmative Defenses. By asserting these Affirmative Defenses, Defendant does not assume any burden of proof not otherwise legally assigned to it.

FIRST DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

SECOND DEFENSE

Plaintiff is not entitled, on the law or the facts, to any of the damages that she claims.

THIRD DEFENSE

Plaintiff's claims are barred, in whole or in part, because Plaintiff has not sustained any injury or damage due to any act or omission of Defendant. In particular, Plaintiff has not pled facts identifying any specific alleged misstatement or omission upon which Plaintiff and/or her prescribing physician(s) saw, read, or relied upon, or that caused her physician(s) to prescribe Injectafer.

FOURTH DEFENSE

Plaintiff's claims are barred, in whole or in part, by the learned intermediary or sophisticated user doctrine. While Defendant did not have a duty to warn, any duty to warn of the known and knowable risks of Injectafer extends, if at all, only to the learned intermediary in this case, who is Plaintiff's prescribing physician(s).

FIFTH DEFENSE

Plaintiff's claims, if permitted to proceed, would deprive Defendant of its rights to substantive and procedural due process of law under the United States and state

Constitutions, because the Complaint fails to state with sufficient particularity the circumstances and communications allegedly constituting fraud and misrepresentation.

SIXTH DEFENSE

Plaintiff's claims are barred, in whole or in part, by the doctrine of federal preemption. The relief sought would impede, impair, frustrate, or burden the effectiveness of federal law, including the Federal Food, Drug and Cosmetic Act ("FDCA") and the regulations under it. Plaintiff's claims are also barred, in whole or in part, because the federal government has preempted the applicable field of law. The FDA is vested with exclusive regulatory authority and has the expertise to determine the content and acceptability of materials disseminated to healthcare providers regarding prescription medications. In particular (but without limitation), any claim that Injectafer should never have been approved, or that the design of Injectafer was defective, are plainly preempted. Furthermore, to the extent that Plaintiff's claims are based on any alleged misrepresentations to the FDA, the claims are barred under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) and other precedent.

SEVENTH DEFENSE

Plaintiff's claims are barred as an impermissible attempt to enforce the FDCA.

EIGHTH DEFENSE

Any award of compensatory or punitive damages in this action would violate the Fourth, Fifth, Eighth, and Fourteenth Amendments to the United States Constitution. An award of punitive damages would violate Defendant's rights to due process, and Plaintiff's claims for punitive damages, thus, are barred by the United States and state Constitutions. Plaintiff's request for actual or compensatory damages violates the Excessive Fines Clause of the

Eighth Amendment to the United States Constitution because the unquantifiable damages sought constitute an excessive and arbitrary punishment that furthers no legitimate purpose and, thus, is an arbitrary deprivation of property.

NINTH DEFENSE

Defendant specifically references all limitations as to punitive or exemplary damages, including those set forth in *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996); *Cooper Industries v. Leatherman Tool Group, Inc*., 532 U.S. 424 (2001) and *State Farm Mut. Automobile Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

TENTH DEFENSE

To the extent that Plaintiff's claims are premised on a theory of liability without actual proof of causation or reliance, such claims violate Defendant's rights to substantive and procedural due process of law and to equal protection under the law.

ELEVENTH DEFENSE

Plaintiff's claims are barred by the doctrine of remoteness or a lack of general and specific causation.

TWELFTH DEFENSE

Defendant is entitled to, and claims the benefit of, all defenses and preemption set forth in or arising from any rule of law or statute in the Commonwealth of Pennsylvania or any state whose laws are deemed to apply.

THIRTEENTH DEFENSE

Plaintiff's claims are barred, in whole or in part, by the applicable prescriptive periods, statutes of repose, or statutes of limitations, or by the doctrine of laches, or any and all legislative or administrative restrictions on the time within which Plaintiff was required to commence an action.

FOURTEENTH DEFENSE

Plaintiff's claims and any relief thereon are barred, in whole or in part, by the doctrines of waiver, estoppel, unclean hands, collateral estoppel, or res judicata.

FIFTEENTH DEFENSE

Plaintiff's claims are barred, in whole or in part, to the extent she was negligent, careless, and at fault, and acted so as to contribute substantially to any alleged risk of injury and damages.

SIXTEENTH DEFENSE

Plaintiff's claims are barred, in whole or in part, because the risk of injuries, if any, to Plaintiff, resulted from pre-existing or related medical conditions or idiosyncratic reactions, and not from any act or omission of any Defendant.

SEVENTEENTH DEFENSE

Plaintiff's claims should be dismissed, reduced, offset, or barred in accordance with the principles of equitable indemnity or comparative contribution under the laws of the Commonwealth of Pennsylvania or any state whose laws are deemed to apply.

EIGHTEENTH DEFENSE

Plaintiff's claims are barred, in whole or in part, because if Plaintiff suffered injuries – which averments are expressly denied—the injuries or risk of injuries were solely caused by and attributed to the unintended, unreasonable, and improper use which Plaintiff or her physician made of Injectafer.

NINETEENTH DEFENSE

The alleged injuries, losses, or damages, if any, were caused by the actions, negligence, carelessness, fault, strict liability, or omissions of third parties over which Defendant has no control or responsibility.

TWENTIETH DEFENSE

Plaintiff's claims are barred, in whole or in part, because Plaintiff has failed to exercise reasonable care and diligence and failed to mitigate her alleged damages.

TWENTY-FIRST DEFENSE

The liability of Defendant, and such liability is expressly denied, for Plaintiff's non-economic loss must be apportioned in accordance with the provisions of the law of Pennsylvania and any other state whose law is deemed to apply.

TWENTY-SECOND DEFENSE

While Defendant denies that it owed the duties raised in the Complaint, Defendant nevertheless discharged, according to law and due care, every duty it may have owed to anyone in connection with the issues raised by the Complaint.

TWENTY-THIRD DEFENSE

Plaintiff's claims are barred, in whole or in part, because Defendant had no duty to warn healthcare providers of risks because it is not the NDA-holder, nor did it market, sell, promote, or distribute Injectafer or ferric carboxymaltose in the United States.

TWENTY-FOURTH DEFENSE

Defendant pleads as a setoff any monies received from collateral sources for the injuries or damages alleged in the Complaint.

TWENTY-FIFTH DEFENSE

Plaintiff's claims are barred, in whole or in part, because Plaintiff would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint.

TWENTY-SIXTH DEFENSE

In the event Defendant is held liable to Plaintiff — and such liability is expressly denied — and any other entity is also found liable, Defendant is entitled to a percentage contribution of the total liability from said entity in accordance with principles of indemnity and contribution as well as pursuant to any other state law deemed to apply.

TWENTY-SEVENTH DEFENSE

Defendant hereby gives notice that it intends to rely upon and incorporate by reference any affirmative defenses that may be asserted by any co-defendant in this lawsuit.

TWENTY-EIGHTH DEFENSE

Defendant gives notice that it intends to raise and rely upon any additional defenses that become available or apparent during discovery and it, thus, reserves the right to amend this pleading and assert such additional defenses.

TWENTY-NINTH DEFENSE

Defendant asserts the provisions of all statutory caps on damages of any sort, including punitive, non-economic or exemplary damages, under the laws of the Commonwealth of Pennsylvania or any state whose law is deemed to apply.

THIRTIETH DEFENSE

Defendant relies upon all defenses made available under the law of the Commonwealth of Pennsylvania.

THIRTY-FIRST DEFENSE

Neither Defendant Vifor International, nor its subsidiaries or affiliates, manufactured, marketed, or distributed Injectafer or ferric carboxymaltose in the United States and thus claims against it are barred.

Dated: June 18, 2021

Respectfully submitted,

/s/ Heather R. Olson

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CERTIFICATE OF SERVICE

I, Heather R. Olson, Esquire, hereby certify that on this 18th day of June, 2021, I electronically filed the foregoing with the Court using the CM/ECF system, and thereby delivered the foregoing by electronic means to all counsel of record.

/s/ Heather R. Olson
Heather R. Olson